NRDC
THE EARTH'S BEST DEFENSE

NATURAL RESOURCES DEFENSE COUNCIL

February 25, 2002

BY FACSIMILE

Office of the Hearing Clerk
US. Environmental Protection Agency
401 M Street, S.W.
Waterside Mall, Room C400
Washington, D.C. 20460

Re: Objections to the Establishment of Tolerances for Halosulfuron-Methyl (OPP 301200), Halosulfuron-Methyl (OPP 301197), and Pymetrozine (OPP 301180).

Dear Hearing Clerk:

Please find enclosed NRDC's objections to the establishment of tolerances for the following pesticide chemical residues: Halosulfuron-Methyl, (OPP 301200) Halosulfuron-Methyl (OPP 301197), and Pymetrozine (OPP 301180). A hard copy has been delivered by messenger as well.

Thank you for your assistance. Please call me at (202) 265-2400 if you have any questions.

Sincerely,

Aaron Colangelo
Staff Attorney

Enclosures (delivered by hand)

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OBJECTIONS
TO THE ESTABLISHMENT OF TOLERANCES
FOR PESTICIDE CHEMICAL RESIDUES

OPP 301200 (Halosulfuron-Methyl)
OPP 301197 (Halosulfuron-Methyl)
OPP 301180 (Pymetrozine)

Pursuant to 21 U.S.C. § 346a(g) and 40 C.F.R. Part 180, the Natural Resources Defense Council (NRDC) makes the following objections:

(1) NRDC objects to the regulation issued under 21 U.S.C. § 346a(d)(4), establishing a tolerance for pesticide chemical residues of halosulfuron-methyl. 66 Fed. Reg. 66,333 (Dec. 26, 2001).

(2) NRDC objects to the regulation issued under 21 U.S.C. §§ 346a(e) & (l)(6), establishing a time-limited tolerance for pesticide chemical residues of halosulfuron-methyl until December 31, 2003. 66 Fed. Reg. 66,778 (Dec. 27, 2001).

(3) NRDC objects to the regulation issued under 21 U.S.C. § 346a(d)(4), establishing a tolerance for pesticide chemical residues of pymetrozine. 66 Fed. Reg. 66,786 (Dec. 27, 2001).

As discussed further below, NRDC requests a waiver of the tolerance objection fees pursuant to 40 C.F.R. 180.33(m). NRDC incorporates by reference the following attachments in support of these objections: NRDC et al., *Petition for a Directive that the Agency Designate Farm Children As a Major Identifiable Subgroup* (Oct. 22, 1998); NRDC et al., *Petition for a Directive that the Agency Consistently Fulfill Its Duty to Retain the Child-Protective Tenfold Safety Factor* (April 23, 1998); NRDC, *Putting*

Children First; NRDC, *Trouble on the Farm*. NRDC reserves the right to submit supplemental information in further support of these objections.

I. INTRODUCTION

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA), the Environmental Protection Agency (EPA) may only establish a tolerance for pesticide chemical residue in or on a food if EPA determines that the tolerance is "safe." 21 U.S.C. § 346a(b)(2)(A)(i). A tolerance will meet this requirement only if "there is a reasonably certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." *Id.* § 346a(b)(2)(A)(ii). The health-protective standard of the FQPA requires EPA to give special consideration to the health of infants and children, and EPA must "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue." *Id.* § 346a(b)(2)(C)(ii)(i).

In establishing new tolerances for halosulfuron-methyl and pymetrozine, published at 66 Fed. Reg. 66,333 (Dec. 26, 2001) (halosulfuron-methyl), 66 Fed. Reg. 66,778 (Dec. 27, 2001) (halosulfuron-methyl), and 66 Fed. Reg. 66,786 (Dec. 27, 2001) (pymetrozine), EPA has violated the requirements of the FQPA. With respect to both pesticides, EPA failed to apply the children's 10X safety factor, acknowledge and consider farm children as a major identifiable subgroup, take into consideration reliable data concerning occupational exposure, or fully assess aggregate exposures. With respect to pymetrozine, EPA additionally failed to regulate on the basis of a no observed effect level (NOEL), protect all infants and children and not just those within a certain

percentile, or guarantee that legal food will be safe food based on exposure to pesticide chemical residues at the tolerance level.

II. GROUNDS FOR THE OBJECTIONS

A. In Establishing These Tolerances, EPA Improperly Failed To Apply The Children's 10X Safety Factor.

In establishing tolerances for both halosulfuron-methyl and pymetrozine, EPA failed to include an additional 10X safety factor for infants and children as required by the FQPA. Under the Food Quality Protection Act's precautionary approach to protecting children, EPA must maintain an additional 10-fold margin of safety in its risk assessments for individual pesticides to "take into account potential pre– and post–natal developmental toxicity and completeness of the data with respect to exposure and toxicity to infants and children." 21 U.S.C. § 346a(b)(2)(C). EPA can use a different margin of safety "only if, on the basis of reliable data, such margin will be safe for infants and children." *Id.* EPA has acknowledged that it lacks necessary data for toxicity to the developing brain and nervous system for both halosulfuron-methyl and pymetrozine, and therefore lacks the "reliable data" necessary under the FQPA to authorize a different margin of safety.

In its 1993 report, Pesticides in the Diets of Infants and Children, the National Academy of Sciences/National Research Council cited strong evidence that pesticide exposures may disrupt the normal development of a child's brain and nervous system. More conclusive evidence has since been published supporting this finding. Studies show that developmental neurotoxicity (DNT) testing is more sensitive, and therefore more appropriate for protecting children's health. DNT testing is essential for pesticides, not only as a measure of toxicity to the developing brain and nervous system, but also as

an often more sensitive measure of developmental and reproductive effects generally. EPA's 10X Task Force recommended that "developmental neurotoxicity testing be included as part of the minimum core toxicology data set for all chemical food-use pesticides for which a tolerance would be set." *See* 10X Task Force, USEPA, *Toxicology Data Requirements for Assessing Risks of Pesticide Exposure to Children's Health (draft)*, Nov. 30, 1998, at 11. In spite of this, and in spite of EPA's own declaration that there is insufficient data for these particular pesticides, the Agency failed to retain the additional FQPA 10X safety factor for either halosulfuron-methyl or pymetrozine.

Developmental neurotoxicity testing is still outstanding for halosulfuron-methyl and pymetrozine; this critical data gap makes it impossible to assess the neurotoxic effects of these pesticides to fetuses, infants, and children. EPA has expressly acknowledged that DNT testing is necessary and required to assess the risks of halosulfuron-methyl and pymetrozine. *See* 66 Fed. Reg. 66,786, 66,791 (Dec. 27, 2001) (stating that there is "a need for a developmental neurotoxicity study" for pymetrozine); 66 Fed. Reg. 66778, 66782 (Dec. 27, 2001) (stating that "the developmental neurotoxicity study is required" for halosulfuron-methyl "to understand what the effect is at a high exposure… level"). At the time of the original notice of registration for pymetrozine in the fall of 1999, EPA imposed a requirement of a DNT study, due October 2001, as a condition of registration. *See* 66 Fed. Reg. 66,786, 66,792 (Dec. 27, 2001). Even though this condition has been unfulfilled, and DNT results are required and overdue, EPA has established new tolerances for pymetrozine. In doing so, EPA failed to apply the required 10X safety factor for children that is intended to compensate for just such data gaps. 21 U.S.C. § 346a(b)(2)(C). For halosulfuron-methyl, there are five other

significant data gaps, in addition to the missing DNT tests. Importantly, no cancer risk assessment was conducted. *See* 66 Fed. Reg. 66,333, 66,335 (Dec. 26, 2001). In addition, for aggregate exposure, EPA acknowledges four outstanding data requirements: (1) "a short-term [residential] risk assessment is required for adults," (*id.* at 66,337); (2) "a short-term [residential] risk assessment is required for infants and children" because of dermal and oral exposure risks (*id.* at 66,337); (3) "an intermediate-term [residential] risk assessment is required for adults," (*id.* at 66,338); and (4) "an intermediate-term [residential] risk assessment is required for infants and children," (*id.* at 66,338).

In addition, for both pesticides, EPA has failed to adequately consider important exposure routes for millions of infants and children, including children living on farms and who accompany their parents into farm fields (see discussion of farm children below), exposure from drift, and drinking water. In light of the incomplete data and potential pre- and post-natal developmental toxicity for both halosulfuron-methyl and pymetrozine, EPA's failure to apply the 10X children's safety factor violates the FQPA.

B. Farm Children Are Especially Vulnerable To Pesticide Exposure, And Are Not Adequately Considered In These Tolerances.

Farm children should be deemed to comprise an especially vulnerable population, and their exposure to halosulfuron-methyl and pymetrozine must be considered in establishing tolerances where data is available. Children who live on or near farms are at risk from airborne pesticide drift when they spend any time outdoors. Pesticides sprayed outdoors may enter houses and concentrate in indoor air. Protection of children necessitates routine, consistent monitoring of ambient air pesticide levels in agricultural regions. In establishing these tolerances for halosulfuron-methyl and pymetrozine, EPA

failed to consider available information concerning the sensitivities and exposures of this major identifiable subgroup of consumers.

The children of farmers, farmworkers and agricultural communities – including over 500,000 children under the age of six – are surrounded by a virtual sea of pesticides. They come in contact with pesticides through residues from their parents' clothing, dust tracked into their homes, contaminated soil in areas where they play, food brought directly from the fields to the table, and contaminated well water. These children are likely to have the highest exposure to pesticides of any group of people in the country. Furthermore, farm children often accompany their parents to work in the fields, raising their pesticide exposures even higher. Many of the children with the greatest pesticide exposures are from migrant farmworker families, who are poor and usually people of color or recent immigrants.

EPA's regulations establishing tolerances for halosulfuron-methyl and pymetrozine fail to consider farm children as a major identifiable subgroup. *See* 66 Fed. Reg. 66,333 (Dec. 26, 2001); 66 Fed. Reg. 66,778 (Dec. 27, 2001); 66 Fed. Reg. 66786 (Dec. 27, 2001).

C. EPA Failed To Consider Worker Risk In Establishing The Tolerances.

The FFDCA requires consideration of worker risk in establishing final tolerances. A tolerance is not considered safe under the statute unless there is a reasonable certainty that no harm will result "from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures *and all other exposures for which there is reliable information.*" 21 U.S.C. § 346a(b)(2)(A)(ii) (emphasis added). Worker exposure is clearly included in this catch-all category of "all other exposures" to be

considered in setting a tolerance. In establishing tolerances for halosulfuron-methyl and pymetrozine, EPA cites no provision of the statute or any other authority to support its interpretation that aggregate exposure "does not include occupational exposure." 66 Fed. Reg. 66,786, 66,787 (Dec. 27, 2001); 66 Fed. Reg. 66,778, 66,779 (Dec. 27, 2001); 66 Fed. Reg. 66,333, 66,334 (Dec. 26, 2001). EPA's failure to consider worker risks in establishing these tolerances violates the FQPA.

D. The Aggregate Risk Assessment Is Inadequate.

The FQPA, 21 U.S.C. § 346a(b)(2)(A)(ii) requires that, to establish a pesticide tolerance, there must be a "reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information." Aggregate exposure is the total exposure to a single chemical or its residues that may occur from dietary (*i.e.*, food and drinking water), residential, and all known or plausible exposure routes (including oral, dermal and inhalation). *See id.* Therefore, in addition to food and water exposures, the aggregate assessment must take into account exposures due to air drift and migration of contaminated soil, residential exposures from registered uses, residential "take-home" exposures to families of those directly exposed to the pesticides through its agricultural uses. Furthermore, the aggregate assessment must consider exposures from uses that do not conform with the label, if there is an indication that such uses occur.

EPA failed to conduct an adequate aggregate assessment in establishing tolerances for halosulfuron-methyl and pymetrozine. None of the three regulations establishing tolerances for halosulfuron-methyl and pymetrozine consider exposure through air drift or migration of contaminated soil. In addition, for pymetrozine, EPA

incorrectly concluded that the new tolerances would not result in any increased residential exposure because the tolerances were not for residential uses. *See* 66 Fed. Reg. 66,786, 66,791 (Dec. 27, 2001). This ignores reliable data concerning take-home exposure resulting from agricultural uses. NRDC's 1998 report, Trouble on the Farm, documents the scientific evidence supporting the potential for take-home exposures from pesticides, even when not registered for residential use (this report is hereby incorporated by reference). EPA similarly ignored take-home exposures to halosulfuron-methyl from agricultural uses. *See* 66 Fed. Reg. 66,333, 66,336 (Dec. 26, 2001). EPA's failure to include all possible routes of exposure to halosulfuron-methyl and pymetrozine has biased the final estimates of aggregate risk so that they understate rather than overstate true risks.

Furthermore, EPA relies on inappropriate assumptions that have the effect of underestimating risk. In assessing aggregate exposures to pymetrozine, EPA assumes that a toddler's hand-to-mouth exposure occurs very few times per hour, and the Agency does not assess other routes of non-dietary oral exposure for infants. *See* 66 Fed. Reg. 66,786, 66,792 (Dec. 27, 2001). This assessment of a child's mouthing behavior is incomplete because it focuses only on hand-to-mouth exposures. *See id.* Children put objects other than fingers in their mouth, and these objects may carry pesticide residues and be ingested. Children also eat "feral" food – food that has been dropped on the floor and which picks up residues from contaminated surfaces. The buried assumptions in EPA's analysis of aggregate exposure for pymetrozine serve to underestimate exposure and therefore underestimate risk, contrary to the requirements of the FQPA.

E. EPA Improperly Failed To Rely On A NOEL For Dietary Risk Estimates.

EPA cannot lawfully establish tolerances in the absence of a No Observed Effects Level (NOEL). The report of the House Committee on Commerce clearly states its intent for all safety factors to be applied to the NOEL. *See* H.R. Rep. No. 104-669, Part 2, at 43, presented to the House on July 23, 1996. By using a NOEL, the risk assessor is assured that regulatory decisions are based on a dose at which no effect is elicited. The use of a LOAEL – Lowest Observed Adverse Effect Level – carries no such assurances. "Adverse" effects are often crude toxicological endpoints, such as death, or dramatic loss of body or organ weight, and are not designed to co-ordinate to the vulnerable points in embryonic development. A LOAEL may represent a dose high enough to elicit significant unpleasant effects, and can not be considered as protective as a true NOEL.

In assessing the chronic risk of short-term aggregate exposure to pymetrozine, EPA relied on a LOAEL instead of a NOEL to evaluate oral exposure. *See* 66 Fed. Reg. 66,786, 66,792 (Dec. 27, 2001). EPA also relied on a LOAEL in evaluating the acute dietary exposure of infants and children. *See id.* Lacking a NOEL for these endpoints, EPA has no scientific basis upon which to conclude that there is a fully safe level at which infants and children will not suffer developmental harm because of pymetrozine exposure. Therefore, EPA cannot make a legal finding that any specific pymetrozine level on food is "safe" for infants and children, or that there is a "reasonable certainty of no harm" to infants and children, at any specific level. As a matter of law, under 21 U.S.C. § 346a(b)(2), EPA may not establish these new tolerances for pymetrozine.

F. EPA Failed To Ensure A Reasonable Certainty Of No Harm For <u>All</u> Infants And Children In Establishing These Tolerances.

Under the FQPA, EPA must ensure that there is a reasonable certainty that no children will be harmed through exposure to pesticide chemical residues. 21 U.S.C. § 346a(b)(2)(C). If the best evidence suggests that thousands of children will exceed the reference dose for a pesticide, EPA is barred by statute from finding a reasonable certainty of no harm to these particular infants and children, and the Agency may not issue a tolerance at that level.

However, in establishing tolerances for pymetrozine, EPA regulates dietary residues of pymetrozine at only the 99th percentile. *See* 66 Fed. Reg. 66,786, 66,788 (Dec. 27, 2001). EPA seeks to mask in this approach the fact that even regulation at the 99th percentile, for a pesticide commonly used on a ubiquitous children's food, means that 1% of all American children under age six (around 240,000 children in all) could exceed the chronic reference dose every day, based on the best information available to the agency. No reading of the FQPA will support any approach that allows thousands of children to exceed the reference dose. Regulating dietary residues of pymetrozine at the 99th percentile violates the FQPA's requirement that EPA "ensure that there is a reasonable certainty that *no harm* will result to infants and children from aggregate exposure to the pesticide chemical residue." 21 U.S.C. § 346a(b)(2)(C)(ii)(I).

G. EPA Failed To Guarantee That Legal Food Will Be Safe Food Based On Exposure To Pesticide Chemical Residues Of Pymetrozine At The Tolerance Level.

To measure both chronic dietary exposure and cancer risk, EPA relied on estimates of "anticipated residues" of pymetrozine. *See* 66 Fed. Reg. 66786, 66788 (Dec. 27, 2001). In doing so, EPA did not account for the dietary exposure of a significant number of consumers who purchase produce at farmers markets, farm stands, and "U-

Pik" farming operations. *See id.* Over 1.9 million people buy vegetable and fruits from nearly 13,000 farmers, at more than 2,000 community-based farmers markets and farm stands in the US. *See* National Association of Farmers' Market Nutrition Programs (http://www.nafmnp.org/). These consumers include pregnant women, infants, and children, and must be protected. By ignoring this significant community of consumers, EPA vastly underestimates dietary exposure and cannot ensure that exposure to residues of pymetrozine at the tolerance level will be safe. Reliance on 21 U.S.C. § 346a(b)(2)(E) to factor in anticipated residues of pymetrozine does not justify ignoring the known dietary exposure of potentially millions of consumers to residues of pymetrozine at the tolerance level. EPA must ensure that the legal level of pesticide chemical residue – the established tolerance levels – are themselves safe. 21 U.S.C. § 346a(b)(2)(A).

III. RELIEF REQUESTED

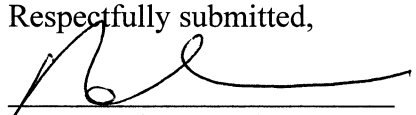
In light of the above outlined statutory violations, NRDC respectfully requests that EPA refrain from establishing the new tolerances for halosulfuron-methyl and pymetrozine until the pesticide tolerances have been assessed and determined to be safe consistent with the requirements of the FQPA.

IV. REQUEST FOR A FEE WAIVER

Pursuant to 40 C.F.R. 180.33(m), NRDC hereby requests a waiver of all tolerance objection fees imposed by 40 C.F.R. 180.33(i). A waiver of fees will promote the public interest. The Natural Resources Defense Council, Inc., is a national non-profit, tax-exempt public policy research and environmental organization. NRDC makes information available to thousands of citizens by means of its numerous and varied publications, educational programs, seminars, and public-interest litigation. These

objections to the tolerances established for halosulfuron-methyl and pymetrozine are intended to benefit primarily the public as opposed to NRDC. As outlined above, these objections challenge EPA regulations that fail to properly implement the FQPA and, as a result, pose threats to the public health, especially children's health. Furthermore, NRDC has no financial interest in the sale, manufacture, or use of halosulfuron-methyl or pymetrozine. Requiring NRDC to pay the fees would work an unreasonable hardship.

Respectfully submitted,



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Dated: February 25, 2002

BEFORE THE

U.S. ENVIRONMENTAL PROTECTION AGENCY

In the Matter of NATURAL RESOURCES DEFENSE COUNCIL, UNITED FARM WORKERS OF AMERICA, FARMWORKER JUSTICE FUND, AMERICAN PUBLIC HEALTH ASSOCIATION, *et al* Petition to the Administrator U.S. Environmental Protection Agency	Docket #_____

PETITION FOR A DIRECTIVE THAT THE AGENCY DESIGNATE FARM CHILDREN AS A MAJOR IDENTIFIABLE SUBGROUP AND POPULATION AT SPECIAL RISK TO BE PROTECTED UNDER THE FOOD QUALITY PROTECTION ACT

1. Introduction

More than 320,000 children under the age of six live on farms in the United States. In addition, many hundreds of thousands of children play or attend schools on or near agricultural land and/or have family members who work on farms or otherwise handle pesticides as part of their jobs. The nation's 2.5 million farm workers have approximately 1 million children living in the U.S.[1] Of the nation's 4.17 million farmworkers and their dependents,[2] an estimated 60 percent live in poverty.[3] Americans cherish the traditional image of a family farm teeming with children, all pitching in to help keep the farm running. Unfortunately, this idyllic image does not reflect the realities of modern chemical agriculture. Approximately 950 million pounds of pesticides (including herbicides, insecticides and fungicides) go into U.S. agricultural production each year,

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[1] Rick Mines, U.S. Dept of Labor, "The Health of Immigrant Children Farmworkers" (1997) at 12.

[2] U.S. Department of Health and Human Services, Public Health Service, Health Resources and Services Administration, Bureau of Health Care Delivery and Assistance, Migrant Health Program, *An Atlas of State Profiles Which Estimate Number of Migrant and Seasonal Farmworkers and Members of their Families*, Table 1 (March, 1990).

[3] U.S. Department of Labor, Office of the Assistant Secretary for Policy, *A Profile of U.S. Farm Workers: Demographics, Household Composition, Income and Use of Services* (1997) at 17.

representing 76 percent of the total pesticide use nationwide.[4] Between 1964 and 1995, the volume of pesticide active ingredients applied in U.S. agriculture more than doubled.[5] This means that children living in agricultural communities are heavily exposed to pesticides, whether or not they work in the fields. This petition uses the term "farm children" to refer to all children living on and near farms, and all children of farmers, farm workers, and others who handle pesticides professionally.

This petition relies on studies and other evidence described in detail in a report by the Natural Resources Defense Council entitled *Trouble on the Farm: Growing Up with Pesticides in Agricultural Communities*. This report collects and reviews a wide range of scientific data on farm children, and finds that these children are at dramatically greater risk than other children for exposure to more pesticides from a wider range of sources. These children make up a significant segment of the U.S. population, and deserve protection no less than other children. The Food Quality Protection Act of 1996 (FQPA) aimed for the first time to protect children when deciding allowable levels of pesticide residues in food. The Act further states that the EPA administrator should consider the special sensitivities and exposure patterns of "major identifiable subgroups of consumers." This petition calls upon EPA to find that farm children are a major identifiable subgroup and must be protected under FQPA when setting allowable levels of pesticide residue in food.

Farm children live on or within a half mile of farmland and come in contact with pesticides residues from their parents' skin and clothing,[6] dust tracked into the house,[7] contaminated soil in outdoor play areas,[8] drift from aerial spraying,[9] indoor air contamination,[10] food eaten directly from the fields,[11] contaminated well-water,[12] and even in breastmilk.[13] In addition, children of all ages spend time in the fields. Children age nine or older may and do work on large farms.[14]

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[4] Aspelin, Arnold, *Pesticide Industry Sales and Usage: 1994 and 1995 market Estimates*, U.S. EPA, at 12. (August 1997).

[5] Id., p. 22.

[6] NIOSH. Report to Congress on Workers' Home Contamination Study Conducted Under The Workers' Family Protection Act (29 U.S.C. §671a). Cincinnati, OH: National Institute for Occupational Safety and Health, 1995.

[7] Simcox NJ, Fenske RA, Wolz SA, Lee IC, Kalman DA. Pesticides in Household Dust and Soil: Exposure Pathways for Children of Agricultural Families. Environ Health Perspect 1995; 103:1126-34.

[8] Id.

[9] Baker L, Fitzell D, Seiber J, Parker T, *et al.* Ambient Air Concentrations of Pesticides in California. Environ Sci Technol 1996; 30:1365-1368.

[10] Camann D, Geno P, Harding H, Giardino N, Bond A, *et al.* A Pilot Study of Pesticides in Indoor Air in Relation to Agricultural Applications. Proc Indoor Air 1993; 2:207-212.

[11] Melnyk LJ, Berry MR, Sheldon LS. Dietary Exposure from Pesticide Application on Farms in the Agricultural Health Pilot Study. J Expo Anal Environ Epidemiol 1997; 7:61-80.

[12] Cohen B, Wiles R. *Tough to Swallow: How Pesticide Companies Profit from Poisoning America's Tap Water.* Washington DC: Environmental Working Group, 1997.

[13] Mattison DR, Wohlleb J, To T, *et al.* Pesticide Concentrations in Arkansas Breast Milk. J Ark Med Soc 1992; 88:553-7.; Rogan WJ. Pollutants in Breast Milk. Arch Pediatr Adolesc Med 1996; 150:981-90.

[14] Approximately 50% of all farms are "small" (*i.e.*, do not meet the 500 man-day requirement to come within the mandate of the Fair Labor Standards Act) and children of any age can work on these farms. Fair Labor Standards Act of 1938, as amended, 29 U.S.C. 213(a)(6). Children as young as 10 may legally work on farms, and the children of farmers may work in the fields at any age. 29 C.F.R. §570.2; Joyner CC. *Child labor in agriculture: characteristics and legality of work.* Washington DC: United States General Accounting Office, 1998:1-18.

Children of any age may work on their parents' farm or on small farms. Children of all ages walk through farmland to school or other destinations. Very young children may accompany their parents to the fields when other childcare options fail.[15] Taken together with children's unique exposure patterns from activity close to the ground, hand-to-mouth behavior, and the fact that, per pound of body weight, children eat, drink and breathe more than adults,[16] farm children may be the most pesticide-exposed group of people in the nation.

An increasing body of scientific evidence, including biomonitoring data and residential exposure studies, indicates that farm children face particularly significant exposures and health risks from pesticides. As many as a dozen different pesticide residues have been found in household dust in farm homes, including agricultural insecticides and herbicides not registered for use in the home.[17] The study tested for four organophosphate insecticides: azinphos-methyl, phosmet, chlorpyrifos, and ethyl parathion. All four were found in dust inside 62 percent of farm homes in a Washington State study, compared with 9 percent of non-farm homes.[18] More than half of the 48 farm homes in the Washington study had residues of one or more of these four organophosphates in the soil where children played next to the house. Less than 20 percent of non-agricultural homes had any of these pesticides in soil. Concentrations of pesticides are significantly higher in farm homes as well. In California, two pesticides, diazinon and chlorpyrifos, were found on the hands of three out of five farmworker children sampled, at levels predicted by a screening risk assessment to result in exposures over the reference dose.[19] None of the children in non-farmworker homes had detectable pesticide residues on their hands. On Midwestern and North Carolina farms, a total of 17 different pesticides, including agricultural herbicides such as atrazine, alachlor, 2,4-D, and dicamba, have been found on the hands of non-working children ranging from ages three to fifteen.[20] In Washington State, two-thirds of farm children under age six had a metabolite of two agricultural organophosphate pesticides in their urine (azinphos-methyl and phosmet), compared with less than half of the non-farm children living in the same area. The average concentration of the residue was four times higher among

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Children younger than 14 may be employed outside of school hours with parental consent or if they work on the same farm as their parents. Children of any age can work on their parent's farm without legal restrictions, even doing hazardous work. (Hazardous jobs include operating heavy equipment like powerful tractors or grain combines; loading or unloading timber; working on a 20 foot high ladder; and mixing, loading or applying certain pesticides.) Twenty eight percent of farm worker children have parents who mix, load or apply pesticides. Mines, *supra*, note 1 at 21.

[15] Pineros y Campesinos Unidos del Noroeste (PCUN), *Testimonies from the Field*, Woodburn, OR 1997.

[16] NRC, *Pesticides in the Diets of Infants and Children*. Washington DC: National Academy Press, 1993.

[17] Camann DE, Harding HJ, Clothier JM, Kuchibhatla RV, Bond AE. Dermal and In-Home Exposure of the Farm Family to Agricultural Pesticides. Measurement of Toxic and Related Air Pollutants 1995; VIP-50:548-554. (showed an average of 17 different pesticides on children's hands); Geno P, Camann D, Harding H, Villalobos K, Lewis R. Handwipe Sampling and Analysis Procedure for the Measurement of Dermal Contact with Pesticides. Arch Environ Contam Toxicol 1996; 30:132-138.

[18] Simcox *et al.*, *supra*, note 7.

[19] Bradman A, Harnly M, Draper W, Seidel S, *et al.* Pesticide Exposures to Children from California's Central Valley: Results of a Pilot Study. J Expos Anal Environ Epi 1997; 7:217-234.

[20] Camann DE, Akland GG, Buckley JD, Bond AE, Mage DT. Carpet Dust and Pesticide Exposure of Farm Children. Intl Soc Exp Anal Ann Mtg, Research Triangle Park, NC, November 5, 1997, 1997.

the farm children.[21] Thus farm children are likely to be exposed to insecticides and herbicides not licensed for household use through numerous non-food sources, at levels higher than other children. In some cases, these exposures appear to result in elevated exposures above current reference doses, and are leading to quantifiable pesticide residues in these children's bodies.

Acting in large measure out of concern for the effects of pesticide exposure on children, Congress unanimously passed the FQPA, which President Clinton signed into law on August 3, 1996. The FQPA amended the nation's pesticide and food safety laws and mandates that protection of infants and children drive decisions about acceptable levels of pesticide residues in our food supply. The FQPA explicitly directs EPA to take into account children's unique exposure patterns and greater potential susceptibility to toxic effects when setting allowable residue levels, or tolerances, for pesticides used on food; to add together a child's exposures to pesticides acting on the body in a common way; and to account for all sources of pesticide exposure, including residential, water, school and air exposure.[22] The Act further provides that, in making tolerance decisions, EPA shall consider (among other relevant factors) "available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers);" "available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources" and "available information concerning the variability of the sensitivities of major identifiable subgroups of consumers. . ."[23]

The undersigned individuals and organizations request in this Petition that the U.S. Environmental Protection Agency (EPA) issue a directive stating that the agency will recognize farm children as a "major identifiable subgroup" under the FQPA §408 (b)(2)(D)(iv, vi & vii), treating them as a 'population at special risk' whose exposures and health status serve as an indicator of potential problems for other population groups and whose health, if protected, would assure a greater level of confidence in protection for the rest of the population. This Petition further requests that, in order to fully protect farm children and all children in making tolerance decisions, EPA:

1) fulfill its non–discretionary duty to use the additional tenfold children's safety factor in establishing, renewing, modifying or revoking tolerances where EPA lacks

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[21] Loewenherz C, Fenske RA, Simcox NJ, Bellamy G, Kalman D. Biological Monitoring of Organophosphorus Pesticide Exposure Among Children of Agricultural Workers in Central Washington State. Environ Hlth Persp 1997; 105:1344-1353.

[22] The Food Quality Protection Act (FQPA) provides that in setting allowable levels of pesticide residue on food, the EPA Administrator "shall ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue," (21 U.S.C. §346a(b)(2)(C), (or commonly referred to as §408 (b)(2)(C)(i)(I–III) of FQPA), "including all anticipated dietary exposures and all other exposures for which there is reliable information" (21 U.S.C. §346a(b)(2)(A)(ii). The Agency is charged with basing its tolerance decisions on available information about: food consumption patterns unique to infants and children; special susceptibilities of infants and children to pesticides, including but not limited to neurological effects; effects of in utero exposure; and the cumulative effects on infants and children of pesticides with a "common mechanism of toxicity." 21 U.S.C. §346a(b)(2)(C)(i)(I–III).

[23] 21 U.S.C. §346a(b)(2)(D)(iv, vi & vii).

complete data on farm children's exposure to a specific pesticide and other substances with a common mechanism of toxicity, as required by the FQPA;[24]

2) in issuing any tolerance, make a specific determination as to the exposures for farm children from all pathways, and assure that these children are fully protected under the tolerance. In particular, EPA should focus attention on data regarding farm children's exposures from four sources: from both residential and agricultural pesticides in soil around homes, schools, parks and other places frequented by farm children; in house dust; in indoor air; and from pesticide drift from spraying. If reliable data on such exposures for farm children are lacking, the EPA will require registrants to secure the necessary data and will not issue a tolerance until such data are available.
3) refuse to register a new pesticide and consider protective restrictions on currently registered pesticides unless there is a validated scientific method available to detect the residues in food;
4) increase research into exposures and health status of farm children, including through biomonitoring of pesticide residues to assess total exposures, with the advice and assistance of farmworkers and their representatives;
5) honor the President's Executive Order on Environmental Justice which directs that when there is a group disproportionately exposed to an environmental toxicant, EPA should fully enforce environmental laws. Specifically, the order states that "each Federal agency shall make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations. . ."[25]

2. Summary of Grounds and Evidence

Population at Special Risk

Children's Sensitivities and Heightened Exposures

Children are more vulnerable to the toxic effects of pesticides for two reasons. First, children are disproportionately exposed to pesticides compared with adults due to their greater intake of food, water, and air per unit of body weight, their greater activity levels, narrower dietary choices, crawling, and hand-to-mouth behavior.[26] Second, fetuses, infants and children are particularly susceptible to toxic effects from many pesticides compared to adults because their immature systems cannot efficiently detoxify and eliminate chemicals, because their organs are still growing and developing, and because they have a longer lifetime to develop health complications

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[24] 21 U.S.C. §346a(b)(2)(C).

[25] Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations: Executive Order 12898. February 11, 1994.

[26] Mott L. Our Children at Risk: The Five Greatest Threats to Children's Health. New York, NY: Natural Resources Defense Council, 1997; NRC, *supra*, note 11; Reigart J. Pesticides and Children. Ped Annals 1995; 24:663-668.

after exposure.[27] Pesticides can have numerous serious health effects, ranging from acute poisoning[28] to cancers,[29] neurological effects,[30] and effects on reproduction and development.[31]

Many pesticides that are never used indoors are tracked into the home and accumulate there at concentrations up to 100-times higher than outdoor levels.[32] In non-agricultural urban or suburban households, an average of twelve different pesticides per home have been measured in carpet dust and an average of eleven different pesticide residues per household have been measured in indoor air in homes where pesticides are used.[33] In an early 1990s nationwide survey of urinary pesticide residues in the general population, metabolites of two organophosphate pesticides, chlorpyrifos and parathion, were detected in 82 percent and 41 percent respectively of the people tested.[34] In a rural community, all 197 children tested had urinary residues of the cancer-causing pesticide pentachlorophenol, all except six of the children had residues of the suspected carcinogen p-dichlorobenzene, and 20 percent had residues of the short-lived outdoor herbicide 2,4-D, which has been associated with non-Hodgkins lymphoma.[35]

Pesticides in Agricultural Areas

Children living in farming areas or whose parents work in agriculture are exposed to pesticides to a greater degree, and from more sources than other children. The outdoor herbicide atrazine was detected inside the houses of all Iowa farm families sampled during the application season.[36] Neurotoxic organophosphate pesticides have been detected on the hands of farm children at levels that could result in exposures above EPA designated 'safe' levels.[37] Metabolites of organophosphate insecticides used only in agriculture were detectable in the urine of two out of every three children of agricultural workers and in four out of every ten children who simply live in an agricultural region.[38] Children of any age can work on their parents' farms or on small farms; children as young as 10 can legally work on large farms, and younger children frequently work illegally or accompany their parents to the fields due to economic necessity and a lack of

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[27] Whitney KD, Seidler FJ, Slotkin TA. Developmental neurotoxicity of chlorpyrifos: cellular mechanisms. Toxicol Appl Pharmacol 1995; 134:53-62; Reigart, *supra*, note 26.

[28] Litovitz TL, Smilkstein M, Felberg L, *et al*. 1996 Annual Report of the American Association of Poison Control Centers Toxic Exposure Surveillance System. Am J Emerg Med 1997; 15:447-500.

[29] Zahm SH, Ward MH. Pesticides and Childhood Cancer. Environ Health Perspect 1998; 106:893-908.

[30] Guillette EA, Meza MM, Aquilar MG, Soto AD, Garcia IE. An Anthropological Approach to the Evaluation of Preschool Children Exposed to Pesticides in Mexico. Environ Health Perspect 1998; 106:347-53.

[31] Pastore LM, Hertz-Picciotto I, Beaumont JJ. Risk of Stillbirth from Occupational and Residential Exposures. Occup Environ Med 1997; 54:511-8; Garry V, Schreinemachers D, Harkins M, Griffith J. Pesticide Appliers, Biocides, and Birth Defects in Rural Minnesota. Environ Hlth Persp 1996; 104:394-399.

[32] Simcox *et al*., *supra*, note 7; Camann DE, Akland GG, Buckley JD, Bond AE, Mage DT. Carpet dust and pesticide exposure of farm children, Intl Soc Exp Anal Ann Mtg, Research Triangle Park, NC, November 5, 1997, 1997.

[33] Whitmore R, Immerman F, Camann D, *et al*. Non-occupational exposures to pesticides for residents of two U.S. cities. Arch Environ Contam Toxicol 1994; 26:47-59.

[34] Hill R, Head S, Baker S, Gregg M, Shealy D, *et al*. Pesticide Residues in Urine of Adults Living in the United States: Reference Range Concentrations. Environ Res 1995; 71:99-108.

[35] Hill R, To T, Holler J, Fast D, *et al*. Residues of Chlorinated Phenols and Phenoxy Acid Herbicides in the Urine of Arkansas Children. Arch Environ Contam Toxicol 1989; 18:469-474.

[36] Camann *et al*., *supra*, note 15.

[37] Bradman *et al*., *supra*, note 14.

[38] Loewenhertz *et al*., *supra*, note 16.

child care options. These practices can result in long-term chronic exposures that can cause more subtle but serious adverse health effects, ranging from neurological and behavioral problems to reproductive dysfunction to cancer. These same practices can also result in acute poisonings and deaths.[39]

FQPA requires that EPA base risk estimates on 1) aggregate exposure to a pesticide from all routes of exposure; and 2) cumulative exposure from all sources to a class of pesticides with a common mechanism of toxicity. EPA's tolerances must be set at levels that will protect *all* fetuses, infants and children, and EPA must consider "major identifiable subgroups of consumers" when setting tolerances. This includes highly-exposed "populations at special risk" such as the children of farmers, agricultural workers, pesticide applicators and landscape workers. These children live and play in home and school environments rich in pesticides and experience quantifiably higher levels of pesticide exposures than other children. They are a major identifiable subgroup of consumers, comprising at least several hundred thousand children. In considering this group and it specific sensitivities, at a minimum EPA must consider exposures from the following sources, discussed in detail in *Trouble on the Farm:*

- contact with parents' contaminated hair, skin and clothing;
- food eaten in the field or brought directly from the field to the table, which may comprise a significant portion of the diets of such children;
- laundering work clothes with children's clothes;
- drinking water contaminated with pesticides, from small water systems, private wells or surface water;
- breathing contaminated outdoor air, fog and drift from spraying;
- breathing contaminated indoor air;
- house dust;
- dermal exposure, especially through pesticides on farm children's hands from contact with contaminated soils, from washing or playing in irrigation ditches and from contact with pets; and
- contaminated breastmilk.

Studies have proven that these can be significant pathways of exposure for farm populations. In particular, EPA must assess the level of home exposure in farm areas even for pesticides not intended for home use. EPA has admitted that it has only limited data on indoor exposures even for chemicals labeled for home use.[40] Yet studies have proven that residues of agricultural chemicals with no licensed home uses can be found in homes and schools at significant levels. For example, in the case of one report from the Agricultural Health Study in Iowa, detection frequency of atrazine in house dust in Iowa farms increased from 75 percent to 100 percent during the application season, the median concentration increased tenfold, and the maximum

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[39] Joyner, CC., Child Labor in Agriculture: Characteristices and Legality of Work. U.S. Genl Acctg Office, 1998: 1-18; Wilk, V., Health Hazards to Children in Agriculture. Am J Ind Med 1993; 24:283-290; Mendoza, M. Toughest Child Labor Laws are Not Enforced. Associated Press, 1997; Pollack, S. McConnell, R., Gallelli, M., Schmidt, J., Obregon, R., Landrigan, P., Pesticide Exposure and Working Conditions Among Migrant Farmworker Children in Western New York State. Am Pub Health Assn Annual Meeting, 1990.

[40] U.S. EPA, Dichlorvos (DDVP): Risk Assessment Issues for the FIFRA Science Advisory Panel, (July 8, 1998)

detected concentrations increased one hundredfold.[41] This suggests that assessing cumulative exposures through the above sources must look beyond heretofore assumed pathways of exposure and should include biomonitoring of farm populations for exposure to both residential and agricultural pesticides. Every EPA model that assumes that air and home exposures to agricultural chemicals are zero cannot be deemed protective, conservative, or reliable, and such models should be revised. In the case of threshold health effects, FQPA directs the Administrator to add an additional tenfold (or other) margin of safety for infants and children "to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children."[42] EPA must retain at least the full 10X for chemicals where the data are insufficient to assure protection of infants and children, and secure complete exposure data so it can determine whether it can satisfy the standard of a reasonable certainty of no harm to infants and children on and near farms when considering aggregate exposure to the pesticides.

Harm to Fetuses Through Exposure of Pregnant Farmworkers

In setting, modifying or revoking tolerances, the FQPA directs the Administrator to consider, *inter alia*, "available information concerning the effects of *in utero* exposure to pesticide chemicals."[43] As described above, EPA must retain the 10X in cases where this data is inadequate to protect fetuses. In explaining its method of implementing the tenfold safety factor to the March 1998 meeting of the Science Advisory Panel (SAP), however, the EPA expressly stated that it would not consider prenatal exposures to the unborn children of pregnant farmworker women because such exposures are "occupational" and hence not within the contemplation of the FQPA.[44] The statutory language which directs the EPA to consider the effects of "in utero" or "prenatal" exposures to pesticides makes no exception for occupational exposures. Nor could such an exception make sense since a fetus or unborn child cannot work.

Indeed, in an analogous context, the California Supreme Court recently held that a child who was injured in utero when his pregnant mother was exposed to carbon monoxide at work could not be prevented from filing suit in tort by the workers compensation bar which prohibits an employee from suing his or her employer.[45] The Court dismissed the notion that the unborn child could be deemed an "employee" as "wholly without merit." The Court also noted that every other court had reached the same conclusion (except one lower California court whose decision was now overruled). Since an unborn child cannot be an "employee," its pesticide exposure cannot be "occupational." Thus, any prenatal exposure to farm children must be considered in applying the 10-fold safety factor and in determining whether a pesticide is safe for infants and children.

Scientific Ability to Detect Residues in Food

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[41] Camann *et al.*, *supra*, note 32.

[42] 21 U.S.C. §346a(b)(2)(C)(ii).

[43] 21 U.S.C. §346a(b)(2)(C)(i)(I–II).

[44] Presentation for the FIFRA Scientific Advisory Panel by Office of Pesticide Programs, Health Effects Division on FQPA Safety Factor for Infants and Children (March 24-25, 1998).

[45] *Snyder v. Michael's Stores, Inc.*, 16 Cal.4th 991, 945 P.2d 781, 68 Cal.Rptr.2d 476 (1997).

In cases where methodology exists to measure pesticides in humans, residues are frequently detected, and correlate with environmental exposure levels.[46] Disturbingly, however, numerous pesticide active ingredients and degradation products are not readily measurable in humans, or are not measurable at all. A recent USDA residue monitoring publication stated: "To analyze the large numbers of samples whose pesticide treatment history is usually unknown, FDA uses analytical methods capable of simultaneously determining a number of pesticide residues. These multi-residue methods (MRMs) can determine about half of the approximately 400 pesticides with EPA tolerances, and many others that have no tolerances." The USDA report mentioned above notes that single residue methods (SRMs) are also available for detecting residues of some pesticides, but these methods "are usually more resource-intensive per residue" and may not be used frequently.[47] An obvious question arises: how it is possible to enforce tolerance limits in pesticides for which there are no practical methods for widespread monitoring? And where there is no test available to detect human exposures, how can children's protection be assured?

Environmental Justice Concerns

President Clinton's Executive Order on Environmental Justice directs: "To the greatest extent practicable and permitted by law, agencies must make achieving [environmental justice] part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects on minority populations and low-income populations. . ." The Executive Order further states that EPA must "improve research and data collection relating to the health and environment of minority populations and low-income populations. . ." and must "ensure greater public participation" in study design.[48] Seventy-eight percent of farm workers are Hispanic.[49] The median income for farm worker families with children is between $12,000 and $15,000 per year.[50] Sixty-eight percent of farm worker children live below the poverty line.[51] The group of farm children addressed in this petition includes the children of farm workers, who fall within both the minority and low-income populations for whose benefit this Executive Order was intended.

3. Actions Requested

We request that EPA:

1) Identify children living on and near farms (and any other highly exposed group of children) as a "major identifiable subgroup" for all FQPA determinations,[52] and designate these children as a "population at special risk" who must be protected in order to fulfill the FQPA requirement that pesticide tolerances provide "a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue."[53] As

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[46] Solomon. G., *Trouble on the Farm: Growing Up with Pesticides in Agricultural Communities*, NRDC (1998) at 39.

[47] U. S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Pesticide Program: *Residue Monitoring 1997* (August 1998), available at http://vm.cfsan.fda.gov/~dms/pes97rep.html.

[48] *Supra* note 25.

[49] *Supra* note 2.

[50] *Supra* note 1 at 14.

[51] *Supra* note 1 at 15.

[52] 21 U.S.C. §346a(b)(2)(C).

[53] 21 U.S.C. §346a(b)(2)(C)(ii)(II).

demonstrated in the attached report, *Trouble on the Farm: Growing Up with Pesticides in Agricultural Communities*, children living on and near farms may have substantially increased exposure to pesticides over other groups of children. These children represent a significant proportion of the population, and any tolerance that does not protect them cannot be found to provide "a reasonable certainty of no harm" under the law.

2) Make a specific finding regarding the exposure of this subpopulation to pesticides from:
   a. presence in the fields for any reason;
   b. food eaten directly from the field, and the amount of such food in farm children's diets;
   c. contact with parents' contaminated hair, skin and clothing;
   d. laundering work clothes with children's clothes;
   e. drinking water contaminated with pesticides, [including from small water systems, private wells or surface water in farm areas];
   f. outdoor air, fog and drift from spraying;
   g. indoor air;
   h. house dust;
   i. dermal exposure, especially through pesticides on farm children's hands from contact with contaminated soils, from washing or playing in irrigation ditches and from contact with pets; and
   j. breastmilk.

   If EPA finds, as a result of this evaluation, that it lacks complete information on any of these documented pathways of exposure, it must apply the tenfold (or greater) safety factor provided for in the Act[54] and require the submission of the missing data. If, as a result of its evaluation of available data, including the scientific literature, EPA finds actual exposures, the agency must set tolerances for that chemical at a level which account for these exposures.

4) In evaluating exposure pathways, identify substances with a common mechanism of toxicity as required by FQPA,[55] and assure that exposure evaluations account for all pathways of exposure to all chemicals with a common mechanism of toxicity.

5) Make available funding for studies to better characterize national baselines for human exposures to common pesticides through programs such as the National Health and Nutrition Examination Survey (NHANES) and extramural research regarding patterns of pesticide exposure and associated health effects in farm children.

4. Petitioners

The **American Federation of Labor and Congress of Industrial Organizations (AFL-CIO)**, Washington.DC, is the nation's umbrella labor organization representing 13 million working Americans in 78 national unions. Many AFL-CIO members, and their families, including some farm workers, are exposed to pesticides in their diet and on the job.

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[54] 21 U.S.C. §346a(b)(2)(C).
[55] 21 U.S.C. §346a(b)(2)(C).

American Public Health Association (APHA), Washington, DC, is the oldest and largest organization of public health professionals in the world, representing more than 50,000 people from over 50 disciplines in public health. The APHA's constitutional purpose is to protect and promote personal and environmental health. The APHA's programs are focused on the review of the scientific bases for public health programs and policies; identification of impending scientific and practice problems and their potential effects on the public and the environment; and advancement of public health practice.

The **Association of Farmworker Opportunity Programs (AFOP)**, Washington, DC, is the national federation of farmworker employment, training and support service organizations in the United States. The AFOP network encompasses over 450 field service offices located in 49 states and Puerto Rico. AFOP directly provides pesticide and other worker safety education and training to migrant and seasonal farmworkers and their family members. Since its pesticide safety training program began in 1994, over 130,000 farmworkers and their family members have been trained. AFOP's mission is to improve the quality of life for migrant and seasonal farmworkers and their families and to enhance the capabilities of the member organizations that serve them through information, education, support, advocacy and representation at the national level.

The Breast Cancer Fund, San Francisco, CA, works nationally and internationally to find better ways to detect, treat, and ultimately, to prevent breast cancer. The Fund identifies and develops start-up funding for innovative research projects in advocacy, education, and patient support.

Center for Sustainable Systems, Berea, KY, is a non-profit organization that works in Kentucky, the tobacco region, and nationally on sustainable agriculture and rural development issues. Its board of directors consists of farmers and people from agriculture extension schools.

The **Chemical Sensitivity Disorders Association (CSDA)**, Arlington, VA, is a 501(c)(3) corporation established to provide information and support to chemically sensitive people (those with environmental illness (EI) or multiple chemical sensitivities (MCS)) to disseminate information to physicians, scientists and other interested persons; and to encourage research on chemical sensitivity disorders and minimizing hazards to human health.

Children's Health Environmental Coalition (CHEC), Malibu, CA

Clean Water Action, San Francisco, CA

Consumers Union, Yonkers, NY, is a non-profit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with information, education and counsel about goods, services, health and personal finances; and to initiate and cooperate with individual and group efforts to maintain and enhance the quality of life for consumers. Consumers Union's income is derived solely from the sale of *Consumer Reports*, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, *Consumer Reports*, with approximately 4.5 million

paid circulation, regularly carries articles on health, product safety, food safety, market place economics and legislative, judicial and regulatory actions which affect consumer welfare.

In September 1998, CU published *Worst First*, an examination of the specific combinations of organophosphate insecticides on particular crops most responsible for dietary risk to children, and recommending alternatives. The January 1998 edition of *Consumer Reports* tested both conventionally produced and organically grown fruits and vegetables for pesticide residues and reported on the improved health standard of the FQPA. In 1996, Consumers Union published *Pest Management at the Crossroads*, which analyzed trends in pest management, identified environmental, health and economic problems created by agricultural pesticide use and established a road map to reduce reliance on chemical pesticides and increase adoption of biointensive integrated pest management by agricultural producers.

Environmental Advocates, Albany, NY, is a New York state-wide not-for-profit organization devoted exclusively to environmental issues. Our more than 7000 individual members include many adults and children inadvertently exposed to pesticides through their diet, contaminated water and air, and institutional use. Such exposure poses risks to their health.

Environmental Defense Center, Santa Barbara, CA, is a non-profit public interest environmental law firm serving San Luis Obispo, Santa Barbara, and Ventura counties in California.

Environmental Research Foundation, Annapolis, MD, is a non-profit organization which provides information on toxic materials and environmental health to grassroots activists across the country. The Environmental Research Foundation publishes Rachel's Environmental and Health Weekly, which has a readership of approximately 20,000.

The **Environmental Working Group** is a nonprofit environmental research organization based in Washington, DC and San Francisco. The Environmental Working Group is a leading content provider for public education campaigns to protect the environment and human health. EWG is a project of the Tides Center, a nonprofit organization based in San Francisco, California.

Farm Without Harm, Watsonville, CA

Farmworker Justice Fund (FJF), Washington, DC, is a private, non-profit organization which was founded in 1981 to improve the living and working conditions of migrant and seasonal farmworkers, focusing especially on occupational health and safety.

Friends of the Earth (FOE), Washington, DC, is a national non-profit advocacy organization with affiliates in nearly 60 countries around the globe. Of the 20,000 plus members and supporters in the United States, many are deeply concerned with issues of pesticide exposures through food and drinking water and anxious to see significant improvements in the regulations meant to protect their families and their children from harm.

Global Resource Action Center for the Environment (GRACE) Factory Farm Project, New York, NY, is very concerned about the impact of environmental contamination on the health of people. GRACE promotes preventative measures to safeguard our air, food, and water. The Factory Farm Project of GRACE works to reverse the trend toward factory farms in order to ensure a safe and healthful food supply, a clean environment and the welfare of farm animals.

Institute for Agriculture and Trade Policy, Minneapolis, MN

Land Stewardship Project, White Bear Lake, MN is a non-profit organization with 1400 members that fosters an ethic and practice of stewardship for land and water and promotes sustainable agriculture and sustainable communities. Land Stewardship Project does grassroots organizing to secure justice and opportunity for farmers and rural citizens.

Massachusetts Association for the Chemically Injured, Inc. (MACI), Reading, MA, is a non-profit statewide support, education, and referral organization for people with multiple chemical sensitivity (MCS), and others who are sensitive to chemcials in the environemt, and others who care about the prevention of chemical injuries. Many of MCS's 120 members have joined because they or their children have MCS. Pesticide exposure has been the precipitating event in causing the disability of many MACI members.

Migrant Farmworker Justice Project, Belle Glade, FL, is a public interest law firm that advocates on behalf of Florida farmworkers in cases involving wages and working conditions, occupational health and safety, and civil rights.

Montana Coalition for Health, Environmental & Economic Rights (Montana-CHEER), Missoula, MT, is a coalition of 17 non-profit organizations representing thousands of Montana citizens. Montana-CHEER is dedicated to protecting the health and environment of western Montana and has worked on variety of toxics issues including pesticide reform.

Mothers and Others for a Livable Planet, New York, NY, is a consumer education organization with 30,000 members concerned about children's health and the environment. Promote consumer choices that are ecologically sound, safe for children and the environment.

National Campaign for Pesticide Policy Reform, Phoenix, AZ, is a non-profit organization dedicated to reduction of pesticide risks and to policies that reduce children's exposures to harmful pesticides.

National Campaign for Sustainable Agriculture, Pine Bush, NY is a network of diverse groups whose mission is to shape national policies, and to foster a sustainable food and agriculture system that is economically-viable, environmentally-sound, socially-just and humane.

The **National Coalition Against the Misuse of Pesticides (NCAMP)**, was established in 1981 as a national membership organization to identify pesticide hazards and promote the adoption of effective and safe pest management strategies. NCAMP provides useful information on pesticides and alternatives to their use, topics also covered in the organization's quarterly

newsmagazine Pesticides and You, and the monthly news bulletin NCAMP's Technical Report. The staff supports local action to promote independent scientific review of the dangers of pesticide exposure and carries out community information and organizing projects to promote alternative pest management. Among its over 1200 members, NCAMP counts people who are adversely affected by pesticides, including vulnerable populations such as children, elderly and the chemically sensitive. These members seek improved regulatory protection from exposure to hazardous pesticides in their land, air, water and food supply.

The **National Coalition for the Chemically Injured (NCCI)**, Arlington, VA, is a 501 (c)(3) corporation founded to foster an active national coalition of support groups and non-profit advocacy organizations that serve the needs of people with chemical sensitivity disorders. NCCI's mission is to promote and facilitate efforts among these organizations to educate the public, media, and elected officials and medical professionals about the need for greater recognition, treatment, accommodation, prevention, and research of chemical injury and chemical sensitivity disorders.

National Environmental Trust is a non-profit, non-partisan organization dedicated to educating the American public on contemporary environmental issues.

National Religious Partnership for the Environment (NRPE), New York, NY

The **Natural Resources Defense Council (NRDC)** is a national, non–profit environmental membership organization with over 400,000 members and contributors nationwide. Many NRDC members, including pregnant women and children, are exposed to pesticides in their diet and through other sources, thereby creating risks to human health.

Northcoast Environmental Center, Arcata, CA, a non-profit environmental education organization established in 1971, has approximately 3000 members in California concerned about pesticide pollution and other environmental concerns. NEC provides information and referrals to members and the public on pesticide issues.

The **Northwest Coalition for Alternatives to Pesticides (NCAP)**, Eugene, OR, is a regional non-profit organization with over 1,500 members and subscribers that works to educate the public about risks presented by the use of pesticides and the viable alternatives to pesticide use.

Ohio Citizen Action, Columbus, OH, is the largest environmental and consumer advocacy group in the state of Ohio with 150,000 members.

The **Oregon Environmental Council (OEC)**, Portland, is Oregon's oldest statewide environmental group. We are a nonpartisan organization with more than 1,500 members throughout the state, working to protect Oregon's clean water and air for future generations. We are currently working with other groups to establish a pesticide use reporting program in the state of Oregon.

The **Palouse-Clearwater Environmental Institute** is a 500-member non-profit organization working in eastern Washington and north Idaho. Our mission is to increase citizen involvment in decisions that affect our region's environment. As part of our Community Food Systems program, we are working to enhance the long-term viability of Inland Northwest food and agricultural systems through consumer education and support of family farmers.

People For Healthy Forests, Sonora, CA, is a non profit organization working to end dependence on herbicide use by the U.S. Forest Service in their vegetation management programs. People For Healthy Forests' Sierra Watershed Health Assessment Project, performs field surveys on the current herbicide spray projects, gathers scientific data to demonstrate the need to end herbicide dependence, trains community members and forest service employees in stream health assessment techniques, and works with other organizations to help support the health of the nation's forests and watersheds and educate the public on the health and safety hazards of pesticide/herbicide usage.

Pesticide Action Network North American (PANNA) Regional Center, is a San Francisco-based organization that serves as one of five independent regional centers of the Pest Action Network International, a coalition of public interest organizations in more than 60 countries. For more than 15 years, PANNA has been working to end unnecessary pesticide use, advance ecological pest control, and promote sustainable agriculture in the United States and around the world by advocating adoption of ecologically sound practices in place of pesticide use. PANNA is action-oriented and information-based. PANNA is made up of 130 affiliate organizations in the U.S., Mexico and Canada, including 88 in the United States.

Pesticide Watch Education Fund, San Francisco, CA, is dedicated to reducing pesticide use and promoting non-toxic alternatives in California.

Physicians for Social Responsibility (PSR), Washington, DC, is a national non-profit organization representing 18,000 health professionals and concerned citizens. PSR works on a wide range of public health issues including efforts to protect children from pesticides and other environmental toxins.

Piñeros y Campesinos Unidos del Noroeste (PCUN), Woodburn, OR, (in English, United Treeplanters and Farmworkers of the Northwest) represents over 4,000 farmworkers in Oregon.

Protect All Children's Environment (PACE), Marion, NC, is an organization founded in 1987 in response to the lack of support and information available to people adversely affected by widespread use of the pesticide chlordane in Texas. Since then PACE has expanded to provide information and support to people with all chemical injuries from across the United States, including information about access to public buildings and medical care. PACE has a particular interest in chemical injuries that affect children.

Safe Schools, Lafayette, LA, advocates for the detoxification of our nation's schools and performs "in-service" training workshops all over the country for educational policymakers, educating them about the environmental health hazards lurking in their schools: pesticides, harsh

cleaning products, synthetic carpeting, synthetic construction materials, molds, etc. Safe Schools believes that every child deserves a safe environment.

Sustainable Food Center, Austin, TX

Union of Concerned Scientists (UCS), Cambridge, MA, is a non-profit organization comprised of some 80,000 scientists and other citizens advocating in a variety of areas for a healthy world and a clean environment. The UCS' agriculture program promotes sustainable agriculture that is not reliant on toxic inputs.

United Farm Workers of America (UFW), Keene, CA, is the largest union of agricultural workers in the United States and has fought for protections from toxic pesticides since its founding in 1963. The lives and health of the union's 26,000 members and their children are directly affected by the use of pesticides in agricultural communities.

United States Public Interest Research Group (US PIRG), Washington, DC, is the national office for the state Public Interest Research Groups. State PIRGs are non-profit, non-partisan consumer and environmental watchdog groups active across the country. US PIRG and the state PIRGs have nearly half a million members nationwide.

Henry A. Wallace Institute for Alternative Agriculture, Washington, DC, is a non-profit, research and education organization established in 1983 to encourage and facilitate the adoption of low-cost, resource-conserving, and environmentally sound farming systems. The Wallace Institute's fundamental goal is to ensure that farm production gains not only are equitable and protective of human health, but also maintain the soil, water, and air on which farming depends.

Washington Toxics Coalition (WTC), Seattle, WA, is a non-profit organization dedicated to protecting public health and preventing pollution in industry, agriculture, and the home. Since 1981 WTC has worked in Washington state to promote alternatives to pesticides. WTC has over 1,000 members.

World Resources Institute (WRI), Washington, DC, is an independent center for policy research and technical assistance on global environmental and development issues. Created in 1982, WRI is dedicated to helping government and private organizations of all types cope with environmental resource and development challenges of global significance.

Zero Population Growth, Washington, DC, is a 30 year-old, non-profit organization working to educate Americans about the issues of human population growth and the imbalance between people and resources.

5. Legal Authority for Petition

The actions for which the undersigned individuals and organizations are petitioning should be construed as a general statement of policy or interpretive rule under the authority of the

Administrative Procedure Act (APA), 5 U.S.C. §553(e). This provision states that all federal agencies shall provide an interested person the right to petition the agency for the issuance of a "rule" under that section. The APA defines "rule" to include general statements of policy and interpretative rules, APA §551(4), but exempts general statements of policy and interpretative rules from the informal notice and comment rule making and effective date procedural requirements that apply to substantive rules. APA §553(b)–(d).

The Attorney General's Manual on the Administrative Procedure Act at 38 (1947), which traditionally is given substantial deference by the courts, clearly states that the APA right to petition applies to interpretative rules and general statements of policy. The APA therefore clearly provides EPA with the authority to issue the requested directive.[56]

Respectfully submitted this 22nd day of October 1998

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ORGANIZATIONS
American Federation of Labor and Congress of Industrial Organizations (AFL-CIO),Washington, DC
American Public Health Association (APHA), Washington, DC
Association of Farmworker Opportunity Programs (AFOP), Washington, DC
The Breast Cancer Fund, San Francisco, CA
Center for Sustainable Systems, Berea, KY
Chemical Sensitivity Disorders Association (CSDA), Arlington, VA
Children's Health Environmental Coalition (CHEC), Malibu, CA
Clean Water Action, San Francisco, CA
Consumers Union, Yonkers, NY
Environmental Advocates, Albany, NY
Environmental Defense Center, Santa Barbara, CA
Environmental Research Foundation, Annapolis, MD
Environmental Working Group, Washington, DC and San Francisco, CA

[56] *See* Panhandlers Producers v. Economic Regulatory Admin, 822 F.2d 1105, 1110 (D.C. Cir. 1987) (agency may announce presumptions through policy statements rather than notice and comment rulemaking).

Farm Without Harm, Watsonville, CA
Farmworker Justice Fund, Washington, DC
Friends of the Earth, Washington, DC
Global Resource Action Center for the Environment (GRACE), New York, NY
Institute for Agriculture and Trade Policy, Minneapolis, MN
Land Stewardship Project, White Bear Lake, MN
Massachusetts Association for the Chemically Injured, Inc. (MACI), Reading, MA
Migrant Farmworker Justice Project, Belle Glade, FL
Montana Coalition for Health, Environmental & Economic Rights (Montana-CHEER), Missoula, MT
Mothers and Others for a Livable Planet, New York, NY
National Campaign for Pesticide Policy Reform, Phoenix, AZ
National Campaign for Sustainable Agriculture, Pine Bush, NY
National Coalition Against the Misuse of Pesticides (NCAMP), Washington, DC
National Coalition for the Chemically Injured (NCCI), Arlington, VA
National Environmental Trust, Washington, DC
National Religious Partnership for the Environment (NRPE), New York, NY
Natural Resources Defense Council (NRDC), Washington, DC
Northcoast Environmental Center, Arcata, CA
Northwest Coalition for Alternatives to Pesticides (NCAP), Eugene, OR
Ohio Citizen Action, Columbus, OH
Oregon Environmental Council, Portland, OR
Palouse-Clearwater Environmental Institute,
Pesticide Action Network North America (PANNA), San Francisco, CA
People For Healthy Forests, Sonora, CA
Pesticide Action Network North American (PANNA), San Francisco, CA
Pesticide Watch Education Fund, San Francisco, CA
Physicians for Social Responsibility (PSR), Washington, DC
Piñeros y Campesinos Unidos del Noroeste (PCUN), Woodburn, OR
Protect All Children's Environment (PACE), Marion, NC
Safe Schools, Lafayette, LA
Sustainable Food Center, Austin, TX
Union of Concerned Scientists (UCS), Cambridge, MA
United Farm Workers of America (UFW), Keene, CA
United States Public Interest Research Group, Washington, DC
Henry A. Wallace Institute for Alternative Agriculture, Washington, DC
Washington Toxics Coalition, Seattle, WA
World Resources Institute (WRI), Washington, DC
Zero Population Growth, Washington, DC

BEFORE THE

U.S. ENVIRONMENTAL PROTECTION AGENCY

In the Matter of NATURAL RESOURCES DEFENSE COUNCIL, *et al* Petition to the Administrator U.S. Environmental Protection Agency	Docket #_____

PETITION FOR A DIRECTIVE THAT THE AGENCY CONSISTENTLY FULFILL ITS DUTY TO RETAIN THE CHILD-PROTECTIVE TENFOLD SAFETY FACTOR MANDATED BY THE FOOD QUALITY PROTECTION ACT

1. Introduction

The undersigned individuals and organizations request in this Petition that the U.S. Environmental Protection Agency (EPA) issue a directive stating that the agency will consistently retain the statutorily mandated tenfold children's protection safety factor in issuing tolerances for pesticides in foods, contained in the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. §346a(b)(2)(C) or §408(b)(2)(C) of FQPA. The tenfold safety factor is a mandatory duty created by passage of the Food Quality Protection Act of 1996 (FQPA). This petition further asks that the agency announce that it will adhere to its non-discretionary duty to retain the FQPA tenfold children's safety factor requirement for all tolerances unless there are reliable data on infants and children's pre- and post-natal exposure and toxicity, as defined below, and as amplified by the recommendations of a blue ribbon panel to be convened as proposed by this petition.

Congress unanimously passed the Food Quality Protection Act, which President Clinton signed into law on 3 August 1996. The FQPA, which amended the nation's pesticide and food safety laws, mandates that protection of infants and children drive decisions about acceptable levels of pesticide residues in our food supply. This law built upon a 1993 study by the National Academy of Sciences (NAS), *Pesticides in the Diet of Infants and Children*, which found that EPA's existing approach to regulating pesticides failed to address adequately the uniqueness of fetuses, infants, and children, and their potential susceptibility to these poisons. The FQPA explicitly directs EPA to take into account children's unique exposure patterns and greater potential susceptibility to toxic effects when setting allowable residue levels, or tolerances, for

pesticides used on food; to add together a child's exposures to pesticides acting on the body in a common way; and to account for all sources of pesticide exposure.

One of the FQPA's most critical provisions for protecting children is that it requires EPA to use an additional, tenfold (10X) margin of safety in its tolerance risk assessments to account for potential pre– and post–natal toxicity and the completeness (or incompleteness) of data on exposure and toxicity with respect to fetuses, infants and children. The agency may use a different safety factor only if "reliable data" justify use of a different margin of safety for children. This means that the law limits a child's total exposure to a particular pesticide used on food to one–tenth of what would otherwise be allowed unless reliable data show that use of an alternative uncertainty factor will be safe for fetuses, infants and children.

Since the 1993 NAS study, exposure and toxicity studies relating to infants and children have provided increasing evidence that children's unique exposure patterns and potentially greater sensitivity to the toxic effects of pesticides warrant the use of additional caution in setting allowable uses of pesticides and allowable levels of pesticide residue in food.[1]

The Food Quality Protection Act provides that in setting allowable levels of pesticide residue on food, the EPA Administrator "shall ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue," (21 USC §346a(b)(2)(C), or §408 (b)(2)(C) of FQPA), "including all anticipated dietary exposures and all other exposures for which there is reliable information" (21 USC §346a(b)(2)(A)(ii), or §408 (b)(2)(A)(ii) of FQPA). The Agency is charged with basing its tolerance decisions on available information about: food consumption patterns unique to infants and children; special susceptibilities of infants and children to pesticides, including but not limited to neurological effects; effects of *in utero* exposure; and the cumulative effects on infants and children of

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[1] *See*, Wallinga, David, *Putting Children First: Making Pesticide Levels in Food Safer for Infants and Children*, Washington, DC: NRDC, 1998. For toxicity, *see, e.g.*, Campbell, C.G., Seidler, F.J., and Slotkin, T.A., "Chlorpyrifos interferes with cell development in rat brain regions," *Brain Research Bulletin* 43:2, 179-189 (1997)(cited in Wiles, R., Davies, K., Campbell, C., *Overexposed: Organophosphate Insecticides in Children's Food*, Washington, D.C.: Environmental Working Group, 1998); Rodier, P.M., "Developing brain as a target of toxicity," *Environ Health Perspect* 103: 73-76 (1995); Leiss, J.K., Savitz, D.A., "Home pesticide use and childhood cancer: a case–control study," *Am J Public Health* 85: 249-252 (1995); Soto, A.M., Chung, K.L., Sonnenschein, C., "The pesticides endosulfan, toxaphene, and dieldrin have estrogenic effects on human estrogen–sensitive cells," *Environ Health Perspect* 102: 380-383 (1994). For exposure, *see, e.g.*, Gurunathan, S., Robson, M., Freeman, N., Buckley, B., Roy, A., Meyer, R., Bukowski, J., Lioy, P.J., "Accumulation of Chlorpyrifos on Residential Surfaces and Toys Accessible to Children," *Environ Health Perspect* 106:1 (January 1998); Blondell J., "Epidemiology of Pesticide Poisonings in the United States, With Special Reference to Occupational Cases," *Occupational Medicine: State of the Art Reviews* 12:2 (1997); Rogan, W.J., "Pollutants in breast milk," *Arch Pediatr Adolesc Med* 150: 981-990 (1996); Simcox, N.J., Fenske, R.A., Wolz, S.A., Lee, I.C., Kalman, D.A., "Pesticides in household dust and soil: exposure pathways for children of agricultural families," *Environ Health Perspect* 103: 1126-1134 (1995); Wiles, R., Davies, K., *Pesticides in Baby Food*, Washington, D.C.: Environmental Working Group, 1995.

pesticides with a "common mechanism of toxicity" (21 USC §346a(b)(2)(C)(i)(I–III), or §408 (b)(2)(C)(i)(I–III) of FQPA).

In addition, as paraphrased earlier, the Act provides that "an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre– and post–natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children." (21 USC §346a(b)(2)(C), or §408 (b)(2)(C) of FQPA).

2. Summary of Grounds and Evidence

On March 24, 1998, EPA presented a draft plan for implementation of the tenfold child–protective safety factor to the FIFRA Science Advisory Panel. This document demonstrates EPA's deficient practices and policies for implementation of the child–protection provisions in the law. The document appears to waive certain fundamental statutory requirements. Specifically, the document fails to require EPA's consistent application of the non–discretionary duty to use the tenfold safety factor in cases where there are not reliable data on pre– and post–natal exposure and toxicity for fetuses, infants and children. For example, EPA failed to make clear that:

- where there are no data or where there are gaps in data, either for particular toxic effects, for age-specific patterns of food consumption or for particular routes of exposure, there cannot be "reliable data";
- where tests to determine the toxicity of a pesticide have only been run on adult animals, there cannot be "reliable data" for assuring safety to the human fetus, infant or child. The FQPA directs EPA to lift the child–protective safety factor "only if" there are "reliable data;" the law does not permit EPA to alter the safety factor based on models or assumptions.

In some cases the EPA may already have ample data to determine that there are substantial threats to health that warrant regulatory action under the FQPA, even without the collection of any additional data or use of safety factors. For many or most organophosphates and carbamates, for example, EPA has substantial data on children's exposure and toxicity regarding these chemicals, data fully adequate to justify immediate regulatory action. The collection of additional data for these chemicals (such as additional children's exposure or toxicity data) would only increase the already–quantified and troubling risks of their use. Any delay in EPA action to reduce those risks is clearly unwarranted.

Despite substantial data, often warranting regulatory action, a recent NRDC study (attached to this petition) found that there often remain significant and recurring gaps in the data available to the Agency on both toxicity and exposure *specific to fetuses, infants, and children.* Fetuses, infants and children have unique periods of vulnerability during the process of development; they may lack the mature protective mechanisms normally present in adults; they may absorb toxic

chemicals more quickly, due to a variety of factors; and children's unique behavior patterns and diet often may give them greater exposure to and risk from toxic chemicals. Thus, the collection of additional data on toxicity and exposure to children for individual pesticides would likely lead to some stricter tolerances. The FQPA neither requires nor justifies regulatory delay in order to collect additional data. Rather, EPA should use the best data available to make decisions now, and where there are gaps in data on children's pre– or post–natal toxicity or exposure, EPA must use the tenfold safety factor to protect children's health.

Gaps in data requirements and the toxicity data derived from them

While the data EPA requires to be collected often demonstrate substantial risks from pesticides without the need to collect additional information, it is important to note that both the type of data required by the Agency and the ways in which those data are developed under Agency guidelines fail to provide, in some cases, even the most basic information about the effect of a chemical *on developing organ systems*. Specifically, few of the EPA toxicity test guidelines require that the manufacturer expose the test animals to a pesticide at all critical stages of development and observe them for the most critical effects of concern to children, including effects on all vital organ systems, effects on learning and memory, and latent effects that may not become evident until late in life or in offspring.[2] (See Table 1, attached.) Further, the series of acute screening tests that EPA often relies upon to trigger decisions on whether or not to require more sensitive testing to better reflect effects on more sensitive groups, including infants and children, are typically performed on adult animals. This is inadequate because some chemicals may have profound effects on a developing fetus or infant at levels which cause little permanent effect in adults.

Gaps in exposure data

Data available to the Agency also fail to adequately address the likely exposure of fetuses, infants and children to pesticide residues from a variety of sources, as required by the FQPA. And despite strong evidence of harmful pesticide contamination in drinking water,[3] EPA often has collected no pesticide–specific data on water–based exposure, rendering it impossible to find that "reliable data" exist to modify the tenfold safety factor.

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[2] Wallinga, David, *Putting Children First: Making Pesticide Levels in Food Safer for Infants and Children*, Washington, DC: NRDC, 1998, pp. 39-40.

[3] *See, e.g.*, Taets, C., Aref, S., Rayburn, A.L., "The Clastogenic Potential of Triazine Herbicide Contaminants Found in Potable Water Supplies," *Environ Health Perspect* 106:4 (1998); United States Geological Survey, *Pesticides in Surface and Ground Water of the United States: Preliminary Results of the National Water Quality Assessment Program (NAWQA)*, Pesticides National Synthesis Project (http://water.wr.usgs.gov/pnsp/gwsw1.html), 1997; Taylor, A.G., "Pesticides In Illinois' Public Water Supplies: Complying With The New Federal Drinking Water Standards," Proceedings of the 1993 Illinois Agricultural Pesticides Conference, pp. 4-10, Urbana, IL: U. of Illinois Cooperative Extension Service, 1993; Cohen, B., Wiles, R., Bondoc, E., *Weed Killers By the Glass: A Citizen's Tap Water Monitoring Project in 29 Cities*, Environmental Working Group, 1995.

EPA also has insufficient data to justify lifting the tenfold children's safety factor due to gaps in data on pesticide exposure from non–dietary sources, including: pesticides in the home, in schools, in yards, parks and playgrounds, and in both indoor and outdoor air. As with food exposures, no integrated database exists within EPA for collecting and collating data on pesticide exposure through non–dietary contaminated media, including indoor and outdoor air, surface water, soil and household dust. EPA also lacks biological monitoring data, especially on infants and children. While EPA can and must make estimates of such non–dietary exposures based upon the best information available to the agency, these gaps, again, make it difficult to add together all sources of exposures, as required by the FQPA if the agency is to modify the tenfold safety factor.

3. Actions Requested

In the face of the significant and recurring data gaps described above with respect to pre– and post–natal toxicity and exposure for fetuses, infants, and children, EPA cannot reduce or modify the tenfold margin of safety on the basis of "reliable data, as required by FQPA. Therefore we petition the Administrator to issue a directive stating that:

a. In its tolerance decisions, EPA will fulfill its non–discretionary duty to use the additional tenfold children's safety factor in establishing, renewing, modifying or revoking tolerances, as required by the Food Quality Protection Act, 21 U.S.C. § 346a(b)(2)(C). EPA will use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, that margin of safety will be safe for infants and children. EPA will maintain the tenfold safety factor unless the Administrator has determined that there are reliable data on pre– and post–natal toxicity and exposure for fetuses, infants, and children, including but not limited to:

   i. actual, recent dietary consumption data for pregnant women and each major age group of infants and children (e.g. 0-6 months, 6-12 months, one–year age groupings for ages 1-5, etc., through adolescence);
   ii. actual, pesticide–specific residue data for the pesticide in foods in which it may be found, especially foods commonly eaten by children;
   iii. actual, pesticide–specific exposure data for other potential routes of aggregate exposure, including exposure of children through water, outdoor air, the indoor environment, playgrounds, schools, and other locations where children may be exposed;
   iv. pre– and post–natal toxicity data on the pesticide, specific to fetuses, infants, and children, including but not limited to special susceptibilities of infants and children to pesticides; neurological effects; effects of *in utero* exposure; and the cumulative effects on infants and children of pesticides with a "common mechanism of toxicity" pursuant to 21 USC §346a(b)(2)(C)(i)(I–III), or §408 (b)(2)(C)(i)(I–III) of FQPA.

   If there are gaps in such data, until their collection EPA must use the tenfold safety factor and must continue to make decisions with respect to these pesticides based upon the best data that are available. Existing data often documents health risks that warrant regulatory

action, without need for collection of additional data. No delays in regulatory action are required or justified in such cases.

b. In order to assist the agency in determining when there are "reliable data" for pre– and post–natal toxicity to fetuses, infants, and children, EPA will immediately convene a blue ribbon panel, comprised of independent pediatricians, pediatric neurologists, pediatric immunologists, pediatric endocrinologists, pediatric toxicologists, and developmental or other biologists with expertise in effects of *in utero* or early childhood exposure to toxic chemicals, and will request a report within 60 days from that panel. This panel will be augmented with EPA developmental toxicologists and pediatric exposure assessors. It will be charged with reviewing the state of the science on what complete and reliable set of toxicity and exposure data would be sufficient to warrant departure from use of the tenfold FQPA children's safety factor. Furthermore:
   i. EPA will convene these experts under the auspices of the Children's Health Protection Advisory Committee, whose charter states that the committee will "advise, consult with and make recommendations to the Agency on issues associated with the development of regulations to address prevention of adverse health effects to children." This group, currently formed and functioning, already includes many of the pediatric experts needed to answer the charge described in (b) above.
   ii. EPA will make the panel's deliberations transparent and public, and its members free of conflicts of interest.

c. Pending completion of this task, EPA will apply the tenfold safety factor as required by the FQPA. Moreover, EPA will make the regulatory decisions within the time frames mandated by the FQPA and FIFRA, whether or not the panel has completed its action.

EPA will immediately finalize its revised pesticide data requirements and its most up–to–date toxicity testing guidelines and, upon receipt of the findings of the panel convened under (b) above, will initiate any additional revisions to the guidelines and data requirements necessary to assure the protection of fetuses, infants and children.

4. Petitioners

The **Agricultural Resources Center** is a North Carolina non-profit, public interest environmental and advocacy organization with special interest in the effects of pesticides and the promotion of sustainable alternatives.

The **American Federation of Labor and Congress of Industrial Organizations (AFL-CIO)** is the nation's umbrella labor organization representing 13 million working Americans in 78 national union. Many AFL-CIO' s members, and their families, including some farm workers, are exposed to pesticides in their diet and on the job.

The **Association of Farmworker Opportunity Programs (AFOP)** is the national federation of farmworker employment, training and support service organizations in the United States. It's network encompasses over 450 field service offices located in 49 states and Puerto Rico. AFOP directly provides pesticide and other worker safety education and training to migrant and seasonal farmworkers and their family members. Since its pesticide safety training program began in 1994, over 130,000 farmworkers and their family members have been trained. AFOP's mission is to improve the quality of life for migrant and seasonal farmworkers and their families and to enhance the capabilities of the member organizations that serve them through information, education, support, advocacy and representation at the national level.

Californians for Pesticide Reform is a broad-based coalition of over 88 organizations, working to protect public health and the environment from dangerous pesticides and promoting alternative methods of pest control in agriculture, homes, schools, forests and urban settings.

California Public Interest Research Group (CalPIRG) is a non-profit, non-partisan public interest watchdog organization with over 70,000 members in California.

California Rural Legal Assistance (CRLA) Foundation represents farmworkers and other low income residents of rural California. The Foundation provides technical assistance to, and engages in research for farmworkers and farmworker advocates on issues of pesticide safety and occupational safety and health.

Center for Science in the Public Interest is a nonprofit organization that focuses on food safety and nutrition. Many of CSPI's million members and subscribers are highly concerned about risks to human health, including those to fetuses, infants and children, posed by pesticide residues in food.

Consumers Union is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with information, education and counsel about goods, services, health and personal finances; and to initiate and cooperate with individual and group efforts to maintain and enhance the quality of life for consumers. Consumers Union's income is derived solely from the sale of *Consumer Reports*, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, *Consumer Reports*, with approximately 4.5 million paid circulation, regularly carries articles on health, product safety, food safety, market place economics and legislative, judicial and regulatory actions which affect consumer welfare.

The January 1998 edition of *Consumer Reports* tested both conventionally produced and organically grown fruits and vegetables for pesticide residues and reported on the improved health standard of the Food quality Protection Act. In 1996, Consumers Union published *Pest Management at the Crossroads*, which analyzed trends in pest management, identified environmental, health and economic problems created by agricultural pesticide use and established a road map to reduce reliance on chemical pesticides and increase adoption of biointensive integrated pest management by agricultural producers.

The **Ecological Health Organization** (ECHO) is a support and advocacy organization for people disabled with Multiple Chemical Sensitivity (MCS). Many of our members experience severe, adverse health reactions when exposed to pesticides.

Environmental Advocates is a New York state-wide not-for-profit organization devoted exclusively to environmental issues. Our more than 7000 individual members include many adults and children inadvertently exposed to pesticides through their diet, contaminated water and air, and institutional use. Such exposure poses risks to their health.

The **Environmental Working Group** is a nonprofit environmental research organization based in Washington, DC and San Francisco. The Environmental Working Group is a leading content provider for public education campaigns to protect the environment and human health. EWG is a project of the Tides Center, a nonprofit organization based in San Francisco, California.

The **Farmworker Justice Fund** is a private nonprofit organization that works to improve the living and working conditions of the nations 4.2 million migrant and seasonal farmworkers and their family members. Many children of farmworkers are exposed to pesticides through their diet, in the labor camps in which they live, in the fields in which they play, in the schools and daycare centers which they attend, and through contact with their parents, especially through contact with their parents clothing, skin and hair.

Friends of the Earth is a national non-profit advocacy organization with affiliates in nearly 60 countries around the globe. Of the 20,000 plus members and supporters in the United States, many are deeply concerned with issues of pesticide exposures through food and drinking water and anxious to see significant improvements in the regulations meant to protect their families and their children from harm.

Physicians for Social Responsibility (PSR) is a national nonprofit organization representing 20,000 health professionals and concerned citizens. PSR works on a wide range of public health issues including efforts to protect children from pesticides and other environmental toxins. The **Greater San Francisco-Bay Area Physicians for Social Responsibility** includes approximately 2000 physicians and other health professionals as chapter members.

Massachusetts Public Interest Research Group (MassPIRG) is a statewide, non-profit, non-partisan environmental and consumer watchdog group with 55,000 members across Massachusetts.

MCS Referral & Resources is a non-profit educational organization devoted to the diagnosis, treatment, accommodation and prevention of Multiple Chemical Sensitivity (MCS) disorders, which affect 3% to 6% of American adults. Pesticide exposures are one of the leading causes of MCS, and the Environmental Protection Agency has identified MCS as the most common chronic effect of exposure to chlorpyrifos, one of the top 4 pesticides in use today.

Michigan Organic Food and Farm Alliance is a membership-funded, non-profit organization whose mission is to educate consumers, growers and retailers on the benefits of organic and locally produced food, and to promote the transition to organic food production and consumption.

Mothers Organized to Stop Environmental Sins (MOSES) is a grassroots nonprofit organization with over 700 members, founded by persons living in and adjacent to Winona, Texas, in order to protect children from the effects of exposure to hazardous substances that are manufactured, used, handled, stored, burned or disposed of in ways that create a real potential for harm to human health and the environment.

The **National Coalition Against the Misuse of Pesticides (NCAMP)** was established in 1981 as a national membership organization to identify pesticide hazards and promote the adoption of effective and safe pest management strategies. NCAMP provides useful information on pesticides and alternatives to their use, topics also covered in the organization's quarterly newsmagazine Pesticides and You, and the monthly news bulletin NCAMP's Technical Report. The staff supports local action to promote independent scientific review of the dangers of pesticide exposure and carries out community information and organizing projects to promote alternative pest management. Among its over 1200 members, NCAMP counts people who are adversely affected by pesticides, including vulnerable populations such as children, elderly and the chemically sensitive. These members seek improved regulatory protection from exposure to hazardous pesticides in their land, air, water and food supply.

The **Natural Resources Defense Council (NRDC)** is a national, non–profit environmental membership organization with over 350,000 members and contributors nationwide. Many NRDC members, including pregnant women and children, are exposed to pesticides in their diet and through other sources, thereby creating risks to human health.

New York Public Interest Research Group (NYPIRG) is a statewide, non-profit, environmental and consumer advocacy organization with 80,000 citizen members in the State of New York.

The **Northwest Coalition for Alternatives to Pesticides (NCAP)** is a regional non-profit organization with over 1,500 members and subscribers that works to educate the public about risks presented by the use of pesticides and the viable alternatives to pesticide use.

The **Oregon Environmental Council** is Oregon's oldest statewide environmental group. We are a nonpartisan organization with more than 1,500 members throughout the state, working to protect Oregon's clean water and air for future generations. We are currently working with other groups to establish a pesticide use reporting program in the state of Oregon.

Pesticide Action Network North American (PANNA) Regional Center, is a San Francisco-based organization that serves as one of five independent regional centers of the Pest Action Network International, a coalition of public interest organizations in more than 60 countries. For more than 15 years, PANNA has been working to end unnecessary pesticide use, advance

ecological pest control, and promote sustainable agriculture in the United States and around the world by advocating adoption of ecologically sound practices in place of pesticide use. PANNA is action-oriented and information-based. PANNA is made up of 130 affiliate organizations in the US, Mexico and Canada, including 88 in the United States.

Pesticide Watch is a nonprofit public interest organization which works with Californians to safeguard our health and environment against dangerous pesticides.

Physicians for Social Responsibility (PSR) is a national nonprofit organization representing 20,000 health professionals and concerned citizens. PSR works on a wide range of public health issues including efforts to protect children from pesticides and other environmental toxins.

Public Voice for Food and Health Policy is a national, nonprofit research and advocacy organization that looks at food and agriculture policy from a consumer perspective. Founded by consumer advocate Ellen Haas in 1982, Public Voice looks at issues involving the way food is grown, how it is processed, how it is marketed, and the adequacy of the food delivery system. It works with both industry and consumer organizations to promote a safer, healthier and more affordable food supply.

Since 1980 **Roseland Organic Farm** has been an 1800-acre, all-organic beef and grain farm, raising, retailing and wholesaling certified organic beef and grain across the nation.
John Clark

United Farm Workers is North America's leading farmworker advocacy organization, representing 26,000 members. For over 30 years UFW has worked to create a safe and just food supply.

United States Public Interest Research Group (US PIRG) is the national office for the state Public Interest Research Groups. State PIRGs are non-profit, non-partisan consumer and environmental watchdog groups active across the country. US PIRG and the state PIRGs have nearly half a million members nationwide.

Wisconsin Strategic Pesticide Information Project (WSPIP) is an organization whose mission is to achieve the establishment of a pesticide database system (PDS) in Wisconsin and to inform the public about pesticides. The purpose of PDS is to provide public information about the location, amounts, and frequency of pesticide use in the urban and rural environment. Specific pesticide use information is necessary for making accurate assessments of human and environmental effects from exposure to pesticides, for validating exposure information, for prioritizing heath and environmental monitoring, and for promoting effective reduced risk pest management practices. Faithful administration of FQPA and the granting of this petition will encourage the collection and disclosure of pesticide use and exposure information.

The **other organizational petitioners** not described above are public interest organizations dedicated to protecting the public from environmental threats.

5. Legal Authority for Petition

The undersigned organizations hereby petition the Administrator of the EPA to issue a directive stating that the agency will consistently fulfill its non–discretionary duty to retain the statutorily mandated tenfold children's protection safety factor in issuing tolerances for pesticides in foods as required by the FFDCA, 21 U.S.C. §346a(b)(2)(C). The Act makes this duty non–discretionary, but allows the agency to adopt a different safety factor only if there are "reliable data" on pre– and post–natal toxicity and exposure to support a finding of safety with another safety factor. The directive for which we are petitioning should be construed as a general statement of policy or interpretive rule under the authority of the Administrative Procedure Act (APA), 5 U.S.C. §553(e). This provision states that all federal agencies shall provide an interested person the right to petition the agency for the issuance of a "rule" under that section. The APA defines "rule" to include general statements of policy and interpretative rules, APA §551(4), but exempts general statements of policy and interpretative rules from the informal notice and comment rule making and effective date procedural requirements that apply to substantive rules. APA §553(b)–(d).

The *Attorney General's Manual on the Administrative Procedure Act* at 38 (1947), which traditionally is given substantial deference by the courts, clearly states that the APA right to petition applies to interpretative rules and general statements of policy. The APA therefore clearly provides EPA with the authority to issue the requested directive. *See,* Panhandlers Producers v. Economic Regulatory Admin, 822 F.2d 1105, 1110 (D.C. Cir. 1987) (agency may announce presumptions through policy statements rather than notice and comment rulemaking).

Respectfully submitted this 23rd day of April 1998,

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ORGANIZATIONS
Agricultural Resources Center, Carrboro, NC

American Federation of Labor and Congress of Industrial Organizations (AFL-CIO), Washington, DC
Association of Farmworker Opportunity Programs (AFOP), Arlington, VA
California Public Interest Research Group (CalPIRG), San Francisco, CA
Californians for Pesticide Reform, San Francisco, CA
CRLA Foundation, Sacramento, CA
Center for Science in the Public Interest, Washington, DC
Consumer's Union, Yonkers, NY
Ecological Health Organization (ECHO), Hebron CT
Environmental Advocates, Albany, NY
Environmental Working Group, Washington, DC
Farmworker Justice Fund, Inc., Washington, DC
Friends of the Earth, Washington, DC
GRACE Public Fund, New York, NY
Greater San Francisco-Bay Area Chapter of Physicians for Social Responsibility, San Francisco, CA
Massachusetts Public Interest Research Group (MassPIRG), Boston, MA
MCS Referral & Resources, Inc., Baltimore, MD
Michigan Organic Food and Farm Alliance, Cassopolis, MI
Mothers Organized to Stop Environmental Sins (MOSES), Dallas, TX
National Coalition Against the Misuse of Pesticides (NCAMP), Washington, DC
National Environmental Trust, Washington, DC
Natural Resources Defense Council (NRDC), Washington, DC
New York Public Interest Research Group, Albany, NY
Northwest Coalition for Alternatives to Pesticides (NCAP), Eugene, OR
Oregon Environmental Council, Portland, OR
Pesticide Action Network, San Francisco, CA
Pesticide Watch, San Francisco, CA
Physicians for Social Responsibility, Washington, DC
Roseland Organic Farm, Cassopolis, MI
United Farm Workers, Washington, DC
United States Public Interest Research Group (US PIRG), Washington, DC
Wisconsin Strategic Pesticide Information Project, Madison, WI